

**EXHIBIT A - Shelby Thames**

<b>Plaintiff</b>	<b>Case No.</b>
Shirley Denton and Marvin Denton	2:12-cv-01719
Brenda Gullett and Carl Gullett	2:12-cv-02027
<del>Yvonne Semere</del>	<del>2:12-cv-02160</del>
Angelia Ramirez, Manuel Ramirez, Angelia M. Ramirez (terminated 10/24/2012), and Manuel M. Ramirez (terminated 10/24/2012)	2:12-cv-02191
Mary Frances Richard, Joseph Richard and Joseph L. Richard (terminated 10/24/2012)	2:12-cv-02192
Dawn Sequino and David M. Sequino	2:12-cv-02193
<del>Susan Struckus and Stanley Struckus</del>	<del>2:12-cv-02194</del>
Mary Ward, Jeffrey Ward and Jeffrey S. Ward (terminated 10/24/2012)	2:12-cv-02198
Leslie Warner, Leslie H. Warner (terminated 10/24/2012)	2:12-cv-02199
Judy Haddon	2:12-cv-02200
<del>Leslie Rodgers and Eric Rodgers</del>	<del>2:12-cv-02221</del>
<del>Mattie Todd and Ronnie Todd</del>	<del>2:12-cv-02242</del>
Kathy Birt and Joseph Birt	2:12-cv-02251
Patricia Kuks and Martin Kuks, Jr.	2:12-cv-02257
Charlotte A. Day and Troy Day	2:12-cv-02264
<del>Ruth Coffman and Anthony Coffman</del>	<del>2:12-cv-02278</del>
<del>Shannon O'Neal Hewatt and James W. Hewatt</del>	<del>2:12-cv-02279</del>
Linda Combs and Greg Combs	2:12-cv-02283
<del>Barbara A. Wilcox and Joseph R. Wilcox</del>	<del>2:12-cv-02300</del>
Karen V. Conley	2:12-cv-02315
Helen Harper	2:12-cv-02316
<del>Deborah Blankenship</del>	<del>2:12-cv-02327</del>
<del>Tammy Carroll and James Carroll, III</del>	<del>2:12-cv-02328</del>
<del>Mary Pritchett</del>	<del>2:12-cv-02329</del>
<del>Christina Tullier</del>	<del>2:12-cv-02331</del>
Helen Van Wyck	2:12-cv-02374
<del>Linda Burroughs and Ralph Burroughs</del>	<del>2:12-cv-02378</del>
<del>Patricia Warren</del>	<del>2:12-cv-02381</del>
<del>Traci Goss and Marty Goss</del>	<del>2:12-cv-02382</del>
<del>Deborah Greene and John Greene</del>	<del>2:12-cv-02386</del>
<del>Geraldine Yaletchko and John Yaletchko</del>	<del>2:12-cv-02401</del>

Bonnie Huggins and Calvin Huggins	2:12-cv-02412
Norma Carroll and Larry Carroll	2:12-cv-02414
Kimberly Stevens	2:12-cv-02424
<del>Stephanie Blanchard and Steven Blanchard</del>	<del>2:12 cv 02429</del>
Katherine Didomizio	2:12 cv 02436
Cynthia Falcon and Raymond Falcon, Sr.	2:12-cv-02446
Melissa Mincey	2:12-cv-02448
Rhonda Arnette and Anthony Arnette	2:12-cv-02475
Dawn Baker and Michael Baker	2:12-cv-02476
<del>Rhonda Harvey and Roger Harvey</del>	<del>2:12 cv 02477</del>
Donna Matthews, Earl Matthews, and Earl D. Matthews (terminated 10/24/2012)	2:12-cv-02478
<del>Terri Milan</del>	<del>2:12 cv 02479</del>
Donna Murphy	2:12-cv-02485
Francesca Bopp	2:12-cv-02486
Elisabeth Payne, Elisabeth G. Payne (terminated 10/24/2012)	<del>2:12 cv 02488</del>
Joanne Phillips	2:12-cv-02489
<del>Martha Brown and Kenneth Brown</del>	<del>2:12 cv 02498</del>
<del>Janie L. Moret and Clarence J. Moret</del>	<del>2:12 cv 02501</del>
Linda Madding	2:12-cv-02512
Shirley L. Knight and George W. Knight	<del>2:12 cv 02515</del>
Rhonda Cooper	2:12-cv-02532
<del>Deborah L. Slone and David K. Slone</del>	<del>2:12 cv 02544</del>
Carla J. Thorpe	<del>2:12 cv 02546</del>
Pamela Harvey and Jackie Lee Harvey, Sr.	<del>2:12 cv 02556</del>
Alice Sue Wilkin	<del>2:12 cv 02563</del>
Dorothy Hunt	<del>2:12 cv 02575</del>
<del>Tammy Jackson and Bryon Jackson</del>	<del>2:12 cv 02576</del>
<del>Patricia Marks and Floyd Marks</del>	<del>2:12 cv 02577</del>
Mary Clayborne	<del>2:12 cv 02579</del>
<del>Wanda Clayborne</del>	<del>2:12 cv 02580</del>
Anita Fisher	2:12-cv-02581
Kathleen Flynn and Albert Young	<del>2:12 cv 02582</del>
Rhonda Garner and Billy Garner	<del>2:12 cv 02583</del>

Trina Hill	2:12-cv-02584
<del>Michelllyn Murphy, Michael Murphy</del>	<del>2:12-cv-02600</del>
<del>Bonita Taylor</del>	<del>2:12-cv-02601</del>
<del>Nancy Rivers, Darryl Rivers</del>	<del>2:12-cv-02602</del>
<del>Rhonda T. Brantley</del>	<del>2:12-cv-02605</del>
<del>Gayle King</del>	<del>2:12-cv-02606</del>
Kandy P. Dotson and Rick Dotson	2:12-cv-02633
Ila Cosgray	2:12-cv-02634
Tabitha Williamson	2:12-cv-02642
Lori Morse	2:12-cv-02657
<del>Nancy Parks</del>	<del>2:12-cv-02660</del>
Joyce Thomas and William Thomas	2:12-cv-02662
Debbie Tomlinson	2:12-cv-02663
<del>Robin Webb and Jack Webb</del>	<del>2:12-cv-02669</del>
<del>Judy Wiley</del>	<del>2:12-cv-02670</del>
Deborah Young and Steven Ray Young, Jr.	2:12-cv-02672
Kathleen Toennies and Glennon Toennies	2:12-cv-02687
Victoria Soltanshahi	2:12-cv-02688
Karen A. Lyszcarsz and Thomas Lyszcarsz	2:12-cv-02689
Barbara Lawyer-Johnson	2:12-cv-02690
<del>Antoinette James and Ronnie James</del>	<del>2:12-cv-02696</del>
<del>Shelia L. Bracato, Shelia L. Bracte (terminated 12/24/2012)</del>	<del>2:12-cv-02697</del>
Brenda Simpson and Ray Simpson (terminated 10/24/2012)	2:12-cv-02716
Susan Walker (deceased)	2:12-cv-02728
Sara Bell and Terrance Bell	2:12-cv-02741
Jennifer Aguilar and Hilario Aguilar	2:12-cv-02742
<del>Emma G. Honeycutt</del>	<del>2:12-cv-02746</del>
<del>Sharon K. Carrell and Timothy T. Carrell</del>	<del>2:12-cv-02751</del>
Dorothy F. Foust	2:12-cv-02752
<del>Monica Lynn Bauernfeind, James Charles Bauernfeind, II, Monica Bauernfeind (terminated 11/15/2012), and James Bauernfeind (terminated 11/15/2012)</del>	<del>2:12-cv-02768</del>
Diana N. Farris	2:12-cv-02776

<del>Dion Cole and Sheldon Cole</del>	<del>2:12-cv-02786</del>
<del>Tammy Coward and Johnny Coward</del>	<del>2:12-cv-02788</del>
<del>Constance Fisher</del>	<del>2:12-cv-02792</del>
Susan Clones	2:12-cv-02799
Kathy Robertson	2:12-cv-02802
<del>Donna Moosman and Joe Moosman</del>	<del>2:12-cv-02805</del>
<del>Linda Heatherly</del>	<del>2:12-cv-02807</del>
<del>Jennifer D. Marshall and David C. Marshall</del>	<del>2:12-cv-02809</del>
Cathy Lynn Stanley	2:12-cv-02817
<del>Lottie Brusseau and Edward Brusseau</del>	<del>2:12-cv-02819</del>
<del>Netti Watts</del>	<del>2:12-cv-02823</del>
<del>Julia Walker and Willis Walker</del>	<del>2:12-cv-02826</del>
Kimberly Hill	2:12-cv-02829
<del>Patricia Caughorn and Stephen Caughorn</del>	<del>2:12-cv-02832</del>
Mattie J. Brooks	2:12-cv-02865
<del>Bonnie S. Smith and Robert G. Smith</del>	<del>2:12-cv-02876</del>
Lisa A. Russell	2:12-cv-02879
<del>Sandra Sweeney</del>	<del>2:12-cv-02880</del>
<del>Kathy Kidd and Phillip Kidd</del>	<del>2:12-cv-02883</del>
<del>Terry Page</del>	<del>2:12-cv-02884</del>
<del>Tymika Tunstall</del>	<del>2:12-cv-02906</del>
<del>Thelma Cole and Harold Cole</del>	<del>2:12-cv-02908</del>
Susan D. Bartley	2:12-cv-02921
<del>Tina M. Douglas</del>	<del>2:12-cv-02922</del>
Dawn Cullipher	2:12-cv-02934
<del>Lillie R. Miller</del>	<del>2:12-cv-02942</del>
Kathy Blake	2:12-cv-02943
<del>Inez Creel and Carlton S. Creel (terminated 10/04/2012), Carlton Creel</del>	<del>2:12-cv-02950</del>
Brenda J. Wooden	2:12-cv-02951
Anne M. Currie	2:12-cv-02955
<del>Audrey Smallridge and Theron Smallridge</del>	<del>2:12-cv-02956</del>
<del>Jamie Rutherford and Steven Rutherford</del>	<del>2:12-cv-02959</del>
<del>Trudy M. Usey and Dale R. Usey</del>	<del>2:12-cv-02960</del>
Janice Fields and Don Fields	2:12-cv-02971
Grethel Taylor	2:12-cv-02975
Shannon L. Smith	2:12-cv-02989

Susan Grizzle, Simon Thomas Grizzle	2:12-cv-02991
Floreen Leland	2:12-cv-03161
Mary Allmon	2:12-cv-02999
<del>Deborah Kissel and Robert Kissel</del>	<del>2:12-cv-03013</del>
<del>Tammy Richmond and Danny Richmond</del>	<del>2:12-cv-03038</del>
April Berry and Danny Berry	2:12-cv-03074
<del>Delilah Bishop and Walter Bishop</del>	<del>2:12-cv-03075</del>
Stephanie Booher and Davin Booher	2:12-cv-03076
<del>Carmen Castillo and Jose L. Castillo</del>	<del>2:12-cv-03077</del>
Araceli Baez	2:12-cv-03078
<del>Judy K. Damron and Benny Damron</del>	<del>2:12-cv-03079</del>
<del>Yolanda Garcia and Edward Garcia</del>	<del>2:12-cv-03080</del>
<del>Phyllis A. King</del>	<del>2:12-cv-03081</del>
<del>Ronda L. Reed</del>	<del>2:12-cv-03082</del>
<del>Catherine L. Young and David Young</del>	<del>2:12-cv-03083</del>
Mary Diana Book	2:12-cv-03085
<del>Lori Ludwig and Mark Ludwig</del>	<del>2:12-cv-03093</del>
Deborah Mattingly and Tony Mattingly	2:12-cv-03097
Melissa Moore	2:12-cv-03108
Carol Noffsinger	2:12-cv-03118
Glenna T. Hensley	2:12-cv-03119
Kimberly Martello and Glen A. Martello	2:12-cv-03122
Tammy Webb-Henson	2:12-cv-03123
Katherine Smallwood, Henry Smallwood, and Henry Smallwood II (terminated 11/05/2012)	2:12-cv-03124
<del>Jeannie Holland</del>	<del>2:12-cv-03125</del>
<del>Julia Smith</del>	<del>2:12-cv-03128</del>
Kelly L. White and John D. White	2:12-cv-03129
<del>Shari Thomas</del>	<del>2:12-cv-03130</del>
Sara Camille Jones	2:12-cv-03131
Christine Webb and Joseph Webb	2:12-cv-03136
<del>Debra Krauser and Stephen Krauser</del>	<del>2:12-cv-03140</del>
Tracy Woosley and Mr. Woosley	2:12-cv-03145

Lydia Blackwell and Douglas Blackwell	<del>2:12-cv-03155</del>
JoAnn S. Bradley	2:12-cv-03162
Geraldean Gaylor	2:12-cv-03163
Christine Walker	2:12-cv-03166

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC.  
PELVIC REPAIR SYSTEMS  
PRODUCT LIABILITY LITIGATION

MDL No. 2327

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THIS DOCUMENT RELATES TO:

Cases Identified in the Exhibit  
Attached Hereto

**MEMORANDUM OPINION AND ORDER**  
**(*Daubert* Motion re: Shelby Thames, Ph.D.)**

Pending before the court is the Motion to Exclude the Opinions and Testimony of Shelby Thames [ECF No. 2039] filed by the plaintiffs. The Motion is now ripe for consideration because briefing is complete.

**I. Background**

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse (“POP”) and stress urinary incontinence (“SUI”). In the seven MDLs, there are more than 75,000 cases currently pending, approximately 30,000 of which are in this MDL, which involves defendants Johnson & Johnson and Ethicon, Inc. (collectively “Ethicon”), among others.

In this MDL, the court’s tasks include “resolv[ing] pretrial issues in a timely and expeditious manner” and “resolv[ing] important evidentiary disputes.” Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict*

*Litigation in Products Liability Cases* 3 (2011). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure. In Pretrial Order (“PTO”) No. 217, the court instructed the parties to file only one *Daubert* motion per challenged expert, to file each motion in the main MDL—as opposed to the individual member cases—and to identify which cases would be affected by the motion. PTO No. 217, at 4.<sup>1</sup>

## II. Preliminary Matters

Before plunging into the heart of the Motion, a few preliminary matters need to be addressed.

I am compelled to comment on the parties’ misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of expert testimony based on its reliability and relevance. In other words, the parties have comparatively examined expert testimony and have largely overlooked *Daubert*’s core considerations for assessing expert testimony. Although I recognize the tendency of my prior evidentiary determinations

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<sup>1</sup> The plaintiffs identified the Wave 1 cases affected by this Motion in their attached Exhibit A [ECF No. 2039-1], which the court has attached to this Memorandum Opinion and Order. At the time of transfer or remand, the parties will be required to designate relevant pleadings from MDL 2327, including the motion, supporting memorandum, response, reply, and exhibits referenced herein.



to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are misplaced, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper for the admission of expert testimony, as well as my duty to "respect[ ] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert testimony and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular expert testimony and objections currently before me, I assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the expert testimony contained therein.

Finally, I have attempted to resolve all possible disputes before transfer or remand, including those related to the admissibility of expert testimony pursuant to *Daubert*. Nevertheless, in some instances I face *Daubert* challenges where my interest in accuracy counsels reserving ruling until the reliability of the expert testimony may be evaluated at trial. At trial, the expert testimony will be tested by

precise questions asked and answered. The alternative of live *Daubert* hearings is impossible before transfer or remand because of the numerosity of such motions in these seven related MDLs. As these MDLs have grown and the expert testimony has multiplied, I have become convinced that the critical gatekeeping function permitting or denying expert testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert testimony offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of “junk science” looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalizations of expert testimony, and incomplete deposition transcripts. This, combined with the above-described practice of recycling expert testimony, objections, and the court’s prior rulings, creates the perfect storm of obfuscation. Where further clarity is necessary, I believe it can only be achieved through live witness testimony—not briefing—I will therefore reserve ruling until expert testimony can be evaluated firsthand.

### **III. Legal Standard**

By now, the parties should be intimately familiar with Rule 702 of the Federal Rules of Evidence and *Daubert*, so the court will not linger for long on these standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her “knowledge, skill, experience, training, or education.” Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

- (1) whether a theory or technique can be or has been tested;
- (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

*Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts “principles and methodology” above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g., Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

#### **IV. Discussion**

Dr. Thames is a polymer chemist with a Ph.D. in organic chemistry. In 1969, Dr. Thames founded the Department of Polymer Science at the University of Southern Mississippi, and he has served as the Dean of the College of Science. Dr.

Thames's has researched and designed polymers for various uses.

**a. Properties**

*First*, the plaintiffs challenge multiple statements made in Dr. Thames's expert report that are related to degradation and the support—or lack thereof—found in Ethicon's seven-year dog study. The plaintiffs argue that this testimony is unreliable because Dr. Thames contradicts himself and misstates the study's findings. I do not find any of Dr. Thames's supposed self-contradictions to warrant exclusion. Nor is Dr. Thames's testimony unreliably contradictory to the extent it uses the dog study to support his opinion that Prolene “does not undergo meaningful or harmful degradation *in vivo*.” Thames Report 6 [ECF No. 2039-3]. I do agree, however, with the plaintiffs' argument that Dr. Thames has occasionally misstated the dog study's specific findings as to molecular weight. Specifically, although the study reported no *significant* difference in molecular weights, Dr. Thames reports the study as finding *no* molecular weight change. *See, e.g.*, Thames Report 9. Insofar as Dr. Thames's testimony mischaracterizes the dog study's results on molecular weight change, it is **EXCLUDED** and the plaintiffs' Motion on this point is **GRANTED**.

*Second*, the plaintiffs challenge the reliability of Dr. Thames's opinion that the data collected from the seven-year dog study “validates toughness improvement after initial implantation.” Mem. 5 [ECF No. 2042] (citing Thames Report 9). The plaintiffs disagree with the manner in which Dr. Thames has defined and measured “toughness.” But the plaintiffs provide no support for their differing conception of the term or how it is most appropriately measured. Additionally, a review of Dr. Thames's

expert report and Ethicon's Response shows that he used a systematic method to plot data collected in the dog study on strength and elongation that could reasonably be said to relate to toughness. Accordingly, the plaintiffs' Motion on this matter is **DENIED**.

*Third*, the plaintiffs challenge Dr. Thames's opinions on translucent flakes detected on Prolene explants and the presence of extrusion lines. These opinions, however, are apparently contained in Dr. Thames's case-specific expert report regarding a particular Wave 1 plaintiff. As such, these objections are not appropriately addressed in the instant *Daubert* motion, which was filed in the main MDL and should challenge general causation opinions only. The plaintiffs' Motion on this matter is **DENIED**. Further, the plaintiffs' Motion, insofar as it relates to the cleaning protocol employed by Dr. Thames in his plaintiff-specific examination of mesh, is similarly **DENIED**.

## **V. Recurring Issues**

Many of the *Daubert* motions filed in this MDL raise the same or similar objections.

One particular issue has been a staple in this litigation, so I find it best to discuss it in connection with every expert. A number of the *Daubert* motions seek to exclude FDA testimony and other regulatory or industry standards testimony. To the extent this Motion raises these issues it is **GRANTED in part** and **RESERVED in part** as described below.

I have repeatedly excluded evidence regarding the FDA's section 510(k)

clearance process in these MDLs, and will continue to do so in these case, a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913, 921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible prejudicial impact under Rule 403). Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See In re C. R. Bard*, 81 F.3d at 920 (“[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value.”). Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors “to erroneously conclude that regulatory compliance proved safety.” *Id.* at 922. Accordingly, expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, is **EXCLUDED**. For the same reasons, opinions about Ethicon’s compliance with or violation of the FDA’s labeling and adverse event reporting regulations are **EXCLUDED**. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue in these cases and runs the risk of misleading the jury and confusing the issues. Insofar as this Motion challenges the FDA-related testimony discussed here, the Motion is **GRANTED**.

A number of experts also seek to opine on Ethicon’s compliance with design control and risk management standards. Some of this testimony involves the FDA’s

quality systems regulations, and some—likely in an attempt to sidestep my anticipated prohibition on FDA testimony—involve foreign regulations and international standards. I find all of this proposed testimony of dubious relevance. Although these standards relate to how a manufacturer should structure and document risk assessment, the standards do not appear to mandate any particular design feature or prescribe the actual balance that must be struck in weighing a product's risk and utility. Nor is it clear that the European and other international standards discussed had any bearing on the U.S. medical device industry when the device in question was being designed.

Nevertheless, because the nuances of products liability law vary by state, I will refrain from issuing a blanket exclusion on design process and control standards testimony, whether rooted in the FDA or otherwise. Each standard must be assessed for its applicability to the safety questions at issue in this litigation, consistent with state law. I am without sufficient information to make these findings at this time. Accordingly, I **RESERVE** ruling on such matters until a hearing, where the trial judge will have additional context to carefully evaluate the relevance and potential prejudicial impact of specific testimony.

Similarly, I doubt the relevance of testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by the above discussion. Again, such matters seem to say very little about the state of the product itself (i.e., whether or not it was defective) when it went on the market. But because the scope

of relevant testimony may vary according to differences in state products liability law, I **RESERVE** ruling on such matters until they may be evaluated in proper context at hearing before the trial court before or at trial.

Additional—and more broad—matters also warrant mention. While some of these concerns may not apply to this particular expert, these concerns are raised so frequently that they are worth discussing here

*First*, many of the motions seek to exclude state-of-mind and legal-conclusion expert testimony. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury’s fact-finding function by allowing testimony of this type, and I do the same here. *E.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g.*, *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) (“[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.”); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) (“Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony.”). Additionally, an expert may not offer expert testimony using “legal terms of art,” such as “defective,” “unreasonably dangerous,” or “proximate cause.” *See Perez v. Townsend Eng’g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

*Second*, and on a related note, many of the motions seek to prohibit an expert from parroting facts found in corporate documents and the like. I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose



of explaining the basis for his or her expert opinions—assuming the expert opinions are otherwise admissible—he or she may not offer testimony that is solely a conduit for corporate information.

*Third*, many of the motions also ask the court to require an expert to offer testimony consistent with that expert's deposition or report or the like. The court will not force an expert to testify one way or another. To the extent an expert offers inconsistent testimony, the matter is more appropriately handled via cross-examination or impeachment as appropriate and as provided by the Federal Rules of Evidence.

*Fourth*, in these *Daubert* motions, the parties have addressed tertiary evidentiary matters like whether certain statements should be excluded as hearsay. The court will not exclude an expert simply because a statement he or she discussed may constitute hearsay. *Cf. Daubert*, 509 U.S. at 595. Hearsay objections are more appropriately raised at trial.

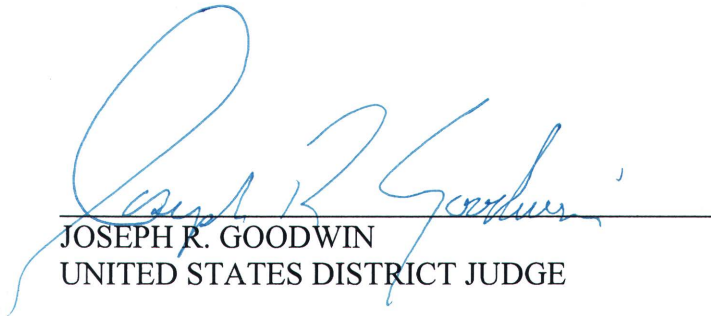
*Finally*, in some of the *Daubert* motions, without identifying the specific expert testimony to be excluded, the parties ask the court to prevent experts from offering other expert testimony that the moving party claims the expert is not qualified to offer. I decline to make speculative or advisory rulings. I decline to exclude testimony where the party seeking exclusion does not provide specific content or context.

## **VI. Conclusion**

The court **DENIES in part, GRANTS in part, and RESERVES in part** the Motion to Exclude the Opinions and Testimony of Shelby Thames [ECF No. 2039].

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 1 cases identified in the Exhibit attached hereto.

ENTER: September 2, 2016



JOSEPH R. GOODWIN  
UNITED STATES DISTRICT JUDGE

## Exhibit A

**Exhibit A - Thames Case Identification**

<b>Case No.</b>	<b>Case Style</b>
2:11-cv-00809	Wilma Johnson v. Ethicon, et al.
2:12-cv-00256	Amy and Brent Holland v. Ethicon, et al.
2:12-cv-00258	Carrie Smith v. Ethicon, et al.
2:12-cv-00261	Mary F. Cone v. Ethicon, et al.
<del>2:12-cv-00265</del>	<del>Doris Chappell Jackson v. Ethicon, et al.</del> WAVE 2
2:12-cv-00276	Cathy and John Warlick v. Ethicon, et al.
2:12-cv-00277	Joy and Kevin Essman v. Ethicon, et al.
2:12-cv-00279	Susan Thaman v. Ethicon, et al.
2:12-cv-00286	Quillan R. and Thomas W. Garnett v. Ethicon, et al.
2:12-cv-00322	Linda B. Ryan v. Ethicon, et al.
2:12-cv-00335	Sandra Wolfe v. Ethicon, et al.
2:12-cv-00337	Kathleen Wolfe v. Ethicon, et al.
2:12-cv-00341	Helen M. Brown and Robert E. Ruttkay v. Ethicon, et al.
2:12-cv-00344	Rose and Jesus Gomez v. Ethicon, et al.
2:12-cv-00347	Deborah and Felipe Lozano v. Ethicon, et al.
2:12-cv-00351	Kathy Barton v. Ethicon, et al.
<del>2:12-cv-00352</del>	<del>Charlotte Hargrove v. Ethicon, et al.</del> CLOSED
2:12-cv-00358	Amanda and Raymond Deleon v. Ethicon, et al.
2:12-cv-00368	Sharon and Michael Boggs v. Ethicon, et al.
2:12-cv-00369	Dawna Hankins v. Ethicon, et al.
2:12-cv-00376	Charlene Logan Taylor v. Ethicon, et al.
<del>2:12-cv-00378</del>	<del>Tina and Kenneth Morrow v. Ethicon, et al.</del> WAVE 2
2:12-cv-00379	Teri Key and Johnny Shively v. Ethicon, et al.
2:12-cv-00380	Terrie S. and Ralph R. Gregory v. Ethicon, et al.
<del>2:12-cv-00381</del>	<del>Susan C. and Leonard Hayes v. Ethicon, et al.</del> CLOSED
2:12-cv-00387	Maru LuEllen and Thomas Lawrence Kilday v. Ethicon, et al.
2:12-cv-00389	Janice Renee Swaney v. Ethicon, et al.
<del>2:12-cv-00397</del>	<del>Deborah A. Smith v. Ethicon, et al.</del> CLOSED
2:12-cv-00401	Carol Jean Dimock v. Ethicon, et al.
2:12-cv-00423	Pamela Free v. Ethicon, et al.
2:12-cv-00443	Holy and Jason Jones v. Ethicon, et al.
2:12-cv-00455	Pamela Gray-Wheeler and Stan Wheeler v. Ethicon, et al.
2:12-cv-00468	Amelia R. and Ernest B. Gonzales v. Ethicon, et al.
2:12-cv-00469	Patricia Tyler v. Ethicon, et al.
2:12-cv-00470	Mary Jane and Daniel Olson v. Ethicon, et al.
2:12-cv-00476	Harriet Beach v. Ethicon, et al.
2:12-cv-00481	Miranda Patterson v. Ethicon, et al.
2:12-cv-00483	Carey Beth and David Cole v. Ethicon, et al.
2:12-cv-00485	Danni Laffoon v. Ethicon, et al.
2:12-cv-00486	Karen and Joel Forester v. Ethicon, et al.
2:12-cv-00489	Melissa and Charles Clayton v. Ethicon, et al.
2:12-cv-00490	Shirley and William Freeman v. Ethicon, et al.
2:12-cv-00491	Gwendolyn T. Young v. Ethicon, et al.
2:12-cv-00493	Nancy and Daniel Hooper v. Ethicon, et al.

Case No.	Case Style
2:12-cv-00494	Penelope Ann Link and Dan Richard Saurino v. Ethicon, et al.
2:12-cv-00495	Andrea Carol and Mark Thomas Chandlee v. Ethicon, et al.
2:12-cv-00496	Sonya M. and James R. Moreland v. Ethicon, et al.
2:12-cv-00497	Dina Sanders Bennett v. Ethicon, et al.
2:12-cv-00498	Myndal Johnson v. Ethicon, et al.
2:12-cv-00499	Kimberly Thomas v. Ethicon, et al.
2:12-cv-00500	Krystal and Gregory Teasley v. Ethicon, et al.
2:12-cv-00501	Jennifer and David Sikes v. Ethicon, et al.
<del>2:12-cv-00504</del>	<del>Donna T. and James W. Pilgreen v. Ethicon, et al.</del> CLOSED
2:12-cv-00505	Mary and Kenneth Thurston v. Ethicon, et al.
<del>2:12-cv-00506</del>	<del>Martha and Stuart Newman v. Ethicon, et al.</del> CLOSED
2:12-cv-00510	Charlene Miracle v. Ethicon, et al.
2:12-cv-00511	Nancy Williams v. Ethicon, et al.
2:12-cv-00516	Patricia Conti v. Ethicon, et al.
2:12-cv-00517	Joann Lehman v. Ethicon, et al.
2:12-cv-00539	Ann Louise Ruppel and Robert Dean Fuller v. Ethicon, et al.
2:12-cv-00540	Nancy and Kenneth Feidler v. Ethicon, et al.
2:12-cv-00547	Brenda and James Riddell v. Ethicon, et al.
2:12-cv-00548	Rhoda Schachtman v. Ethicon, et al.
2:12-cv-00554	Sharon and Gardner Carpenter v. Ethicon, et al.
2:12-cv-00555	Carolyn Sue Doyle v. Ethicon, et al.
2:12-cv-00567	Noemi and Cesar Padilla v. Ethicon, et al.
2:12-cv-00571	Mary Catherine Wise v. Ethicon, et al.
2:12-cv-00591	Beverly Kivel v. Ethicon, et al.
2:12-cv-00594	Frances Ann and Herman Cortez v. Ethicon, et al.
2:12-cv-00595	Mary and Thomas Hendrix v. Ethicon, et al.
2:12-cv-00601	Deanna Jean and Bennie G. Thomas v. Ethicon, et al.
2:12-cv-00609	Patricia O. Powell v. Ethicon, et al.
2:12-cv-00651	Robin Bridges v. Ethicon, et al.
2:12-cv-00652	Maria C. and Mark A. Stone v. Ethicon, et al.
2:12-cv-00654	Stacy and Kevin Shultis v. Ethicon, et al.
2:12-cv-00657	Judy G. Williams v. Ethicon, et al.
2:12-cv-00663	Ana Ruebel v. Ethicon, et al.
2:12-cv-00666	Donna and Leon Loustaunau v. Ethicon, et al.
<del>2:12-cv-00669</del>	<del>Teresa and Ricky J. Stout v. Ethicon, et al.</del> CLOSED
<del>2:12-cv-00679</del>	<del>Lisa and Henry Stevens v. Ethicon, et al.</del> CLOSED
2:12-cv-00683	Louise Grabowski v. Ethicon, et al.
2:12-cv-00736	Karen and Thomas Daniell v. Ethicon, et al.
2:12-cv-00737	Beth and Stuart Harter v. Ethicon, et al.
2:12-cv-00738	Sheri and Gary Scholl v. Ethicon, et al.
2:12-cv-00746	Margaret Kirkpatrick v. Ethicon, et al.
2:12-cv-00747	Karyn E. and Douglas E. Drake v. Ethicon, et al.
2:12-cv-00748	Myra abd Richard Byrd v. Ethicon, et al.
2:12-cv-00749	Jennifer D. and Willem C.J. Van Rensburg v. Ethicon, et al.

Case No.	Case Style
2:12-cv-00751	Raquel and Ernesto De La Torre v. Ethicon, et al.
2:12-cv-00755	Cheryl Lankston v. Ethicon, et al.
2:12-cv-00756	Dee and Michael Woolsey v. Ethicon, et al.
2:12-cv-00757	Barbara Jean and Keith Bridges v. Ethicon, et al.
2:12-cv-00759	Diane and Robert Matott v. Ethicon, et al.
2:12-cv-00760	Lois and Gerald Durham v. Ethicon, et al.
2:12-cv-00761	Barbara J. and Gary L. Ware v. Ethicon, et al.
2:12-cv-00762	Janet D. Jones v. Ethicon, et al.
2:12-cv-00765	Rachel and Dwan Taylor v. Ethicon, et al.
2:12-cv-00766	<del>Kimberly Garnto v. Ethicon, et al.</del> CLOSED
2:12-cv-00767	<del>Rebecca and Charles Oehring v. Ethicon, et al.</del> CLOSED
2:12-cv-00768	<del>Sandra and Christian LaBadie v. Ethicon, et al.</del> CLOSED
2:12-cv-00769	Kimberly T. Burnham v. Ethicon, et al.
2:12-cv-00772	Harmony Minniefield v. Ethicon, et al.
2:12-cv-00773	Tina and Keith Patterson v. Ethicon, et al.
2:12-cv-00779	Dee and Timothy McBrayer v. Ethicon, et al.
2:12-cv-00783	Wendy Hagans v. Ethicon, et al.
2:12-cv-00784	<del>Schultz et al v. Ethicon, Inc. et al</del> CLOSED
2:12-cv-00786	Swint et al v. Ethicon, Inc et al
2:12-cv-00787	Joplin v. Ethicon, Inc et al
2:12-cv-00799	Quijano v. Ethicon, Inc. et al
2:12-cv-00800	Morrison et al v. Ethicon, Inc et al
2:12-cv-00806	Hill et al v. Ethicon, Inc. et al
2:12-cv-00807	Sweeney et al v. Ethicon, Inc. et al
2:12-cv-00811	Zoltowski et al v. Johnson & Johnson et al
2:12-cv-00821	Barr et al v. Ethicon, Inc. et al
2:12-cv-00828	<del>Nix et al v. Ethicon, Inc. et al</del> CLOSED
2:12-cv-00829	Georgilakis et al v. Ethicon, Inc et at
2:12-cv-00830	<del>Parrilla v. Ethicon, Inc. et al</del> CLOSED
2:12-cv-00842	Stubblefield v. Ethicon, Inc. et al
2:12-cv-00846	Raines et al v. Ethicon, Inc. et al
2:12-cv-00848	Fisk v. Ethicon, Inc et al
2:12-cv-00854	Ballard et al v. Ethicon, Inc et al
2:12-cv-00856	Massicot v. Ethicon, Inc. et al
2:12-cv-00859	<del>Olmstead v. Ethicon, Inc. et al</del> CLOSED
2:12-cv-00860	Pelton v. Ethicon, Inc. et al
2:12-cv-00861	<del>Smith et al v. Ethicon, Inc. et al</del> CLOSED
2:12-cv-00863	Gunter et al v. Ethicon, Inc
2:12-cv-00864	Nolan v. Ethicon, Inc. et al
2:12-cv-00867	Rock v. Ethicon et al
2:12-cv-00873	Walker et al v. Ethicon, Inc. et al
2:12-cv-00875	Holzerland et al v. Ethicon, Inc. et al
2:12-cv-00876	Hoy et al v. Ethicon, Inc. et al
2:12-cv-00878	Fox et al v. Johnson & Johnson, Inc. et al

Case No.	Case Style
2:12-cv-00880	Massey et al v. Ethicon, Inc. et al
2:12-cv-00883	Wroble et al v. Ethicon, Inc et al
2:12-cv-00886	Umberger et al v. Ethicon, Inc. et al CLOSED
2:12-cv-00887	Kaiser et al v. Johnson & Johnson et al
2:12-cv-00888	Bruhn et al v. Ethicon, Inc et al
2:12-cv-00899	Barker et al v. Ethicon, Inc. et al
2:12-cv-00921	Wilson v. Ethicon, Inc et al CLOSED
2:12-cv-00923	Atemnkeng et al v. Ethicon, Inc. et al CLOSED
2:12-cv-00931	Collins v. Ethicon, Inc. et al
2:12-cv-00938	Kriz et al v. Ethicon, Inc. et al
2:12-cv-00939	Reyes et al v. Ethicon, Inc. et al
2:12-cv-00956	Justus v. Ethicon, Inc. et al
2:12-cv-00957	Funderburke v. Ethicon, Inc. et al
2:12-cv-00958	White et al v. Ethicon, Inc. et al
2:12-cv-00960	Amsden et al v. Ethicon, Inc. et al
2:12-cv-00961	Greene v. Ethicon, Inc. et al
2:12-cv-00967	Shepherd v. Ethicon, Inc. et al
2:12-cv-00995	Blake et al v. Ethicon, Inc. et al
2:12-cv-00997	Springer et al v. Ethicon, Inc. et al
2:12-cv-01004	Frye v. Ethicon, Inc. et al
2:12-cv-01011	Hankins et al v. Ethicon, Inc. et al
2:12-cv-01013	Lee et al v. Ethicon, Inc. et al
2:12-cv-01018	Gwinn et al v. Ethicon, Inc. et al CLOSED
2:12-cv-01021	Ruiz v. Ethicon, Inc. et al
2:12-cv-01023	Burkhart v. Ethicon, Inc. et al
2:12-cv-01052	Babcock v. Ethicon, Inc. et al
2:12-cv-01053	Baugher v. Ethicon, Inc. et al
2:12-cv-01071	Schnering et al v. Ethicon, Inc. et al
2:12-cv-01081	Dixon v. Ethicon, Inc. et al
2:12-cv-01088	Wheeler et al v. Ethicon, Inc. et al
2:12-cv-01090	Wright v. Ethicon, Inc. et al
2:12-cv-01119	Rhynehart v. Ethicon, Inc. et al
2:12-cv-01121	Guinn v. Ethicon, Inc. et al
2:12-cv-01124	Bellito-Stanford et al v. Ethicon, Inc. et al
2:12-cv-01145	Constance Daino v. Ethicon, Inc. et al
2:12-cv-01146	Monica Freitas v. Ethicon, Inc. et al
2:12-cv-01148	Denise Sacchetti v. Ethicon, Inc. et al
2:12-cv-01149	Cindy Smith v. Ethicon, Inc. et al
2:12-cv-01150	Roberta Warmack v. Ethicon, Inc. et al
2:12-cv-01151	Laura Waynick v. Ethicon, Inc. et al
2:12-cv-01171	Patti Ann Phelps v. Ethicon, Inc. et al
2:12-cv-01198	Stacy Pangborn v. Ethicon, Inc. et al
2:12-cv-01199	Lisa Thompson v. Ethicon, Inc. et al
2:12-cv-01202	Diane Kropf v. Ethicon, Inc. et al

Case No.	Case Style
2:12-cv-01203	Joan Adams v. Ethicon, Inc. et al
2:12-cv-01206	Jeanie Holmes v. Ethicon, Inc. et al
2:12-cv-01215	Karen Bollinger v. Ethicon, Inc. et al
2:12-cv-01216	Christine Wiltgen v. Ethicon, Inc. et al
2:12-cv-01225	Ida Deanne Evans v. Ethicon, Inc. et al
<del>2:12-cv-01262</del>	<del>Saundra Landes v. Ethicon, Inc. et al</del> CLOSED
2:12-cv-01267	Angela Coleman v. Ethicon, Inc. et al
2:12-cv-01273	Rebekah Barlett v. Ethicon, Inc. et al
2:12-cv-01274	Janice Colonna v. Ethicon, Inc. et al
2:12-cv-01275	Long v. Johnson & Johnson et al
2:12-cv-01277	Duncan v. Ethicon, Inc. et al
2:12-cv-01278	Nix v. Ethicon, Inc. et al
2:12-cv-01279	Bertoni et al v. Ethicon, Inc. et al
2:12-cv-01283	Cyrus v. Ethicon, Inc. et al
2:12-cv-01284	<del>Floyd</del> v. Ethicon, Inc. et al Judith Gowin
2:12-cv-01285	Simpson et al v. Ethicon, Inc. et al
2:12-cv-01286	Wilson v. Ethicon, Inc. et al
2:12-cv-01293	Costello v. Ethicon, Inc. et al
<del>2:12-cv-01294</del>	<del>Herrera-Nevarez v. Ethicon, Inc</del> CLOSED
2:12-cv-01299	Destefano-Rasten et al v. Ethicon, Inc. et al
2:12-cv-01304	Irwin et al v. Ethicon, Inc. et al
2:12-cv-01305	Lager v. Ethicon, Inc. et al
2:12-cv-01311	Ridgley et al v. Ethicon, Inc. et al
2:12-cv-01318	<del>Banks</del> v. Johnson & Johnson, Inc. et al Marie Smith



## Exhibit C

### Index of Relevant Pleadings related to Shelby Thames, Ph.D.

Judge Goodwin instituted a series of Waves in MDL 2327 wherein he identified hundreds of cases per Wave subject to discovery and motion practice deadlines. As part of the Wave process, Judge Goodwin required parties to file one general causation *Daubert* motion per expert per Wave in the main MDL, rather than in each individual Wave case. Parties were required to identify the cases in each Wave to which a particular *Daubert* motion applied. The court has identified below, the relevant *Daubert* pleadings filed in each Wave (and in many cases ultimately adopted in subsequent Waves) for the court receiving this case on remand or transfer.

Wave 1	Date	WVSD ECF No.
Motion	4/21/16	2039
Memorandum	4/21/16	2042
Response	5/9/16	2187
Reply	5/16/16	2247
Mem Op & Ord	9/2/16	2723

Wave 2	Date	WVSD ECF No.	Comment
Motion	7/21/16	2455	Does not adopt
Memorandum	7/21/16	2458	Does not adopt
Response	8/8/16	2553	Does not adopt
Reply	8/18/16	2621	Does not adopt
Mem Op & Ord	3/30/17	3563	Adopts ECF No. 2723

Wave 3	Date	WVSD ECF No.	Comment
Motion	9/19/16	2839	Does not adopt
Memorandum	9/19/16	2841	Does not adopt
Response	10/11/16	2957	Does not adopt
Reply	10/21/16	3037	Adopts in part ECF No. 2621